No. 2013-1089

IN THE

United States Court of Appeals for the Federal Circuit

TAKEDA PHARMACEUTICAL COMPANY LIMITED,
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,
TAKEDA PHARMACEUTICALS, LLC,
TAKEDA PHARMACEUTICALS AMERICA, INC.,
and ETHYPHARM, S.A.,

Plaintiffs-Appellees,

v.

ZYDUS PHARMACEUTICALS USA, INC.,
and CADILA HEALTHCARE, LIMITED,

Defendants-Appellants.

Appeal from the United States District Court
for the District of New Jersey
Case No. 3:10-cv-1723
District Judge Joel A. Pisano

NONCONFIDENTIAL BRIEF FOR APPELLEES

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January 25, 2013

Counsel for Appellees

CERTIFICATE OF INTEREST

Counsel for appellees hereby certifies as follows:

1. The full name of every party represented is: Takeda Pharmaceutical Co. Ltd., Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals America, Inc., and Ethypharm, S.A.

2. The real parties in interest are: Takeda Pharmaceutical Co. Ltd., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals America, Inc., and Ethypharm, S.A.

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the parties I represent are as follows:

a. Takeda Pharmaceutical Co. Ltd. No company owns 10% or more of the stock of Takeda Pharmaceutical Co. Ltd.

b. Takeda Pharmaceuticals North America, Inc. Takeda Pharmaceuticals North America, Inc., has changed its name to Takeda Pharmaceuticals U.S.A., Inc. Takeda Pharmaceuticals U.S.A., Inc., is a wholly owned subsidiary of Takeda America Holdings, Inc., which is a wholly owned subsidiary of Takeda Pharmaceutical Co. Ltd.

c. Takeda Pharmaceuticals LLC. Takeda Pharmaceuticals LLC is owned by Takeda Pharmaceuticals U.S.A., Inc., and its wholly owned subsidiary, Takeda Pharmaceuticals America, Inc. Takeda Pharmaceuticals U.S.A., Inc., is a

CERTIFICATE OF INTEREST – Continued

wholly owned subsidiary of Takeda America Holdings, Inc., which is a wholly owned subsidiary of Takeda Pharmaceutical Co. Ltd.

d. Takeda Pharmaceuticals America, Inc. Takeda Pharmaceuticals America, Inc., is a wholly owned subsidiary of Takeda Pharmaceuticals U.S.A., Inc., which is a wholly owned subsidiary of Takeda America Holdings, Inc., which is a wholly owned subsidiary of Takeda Pharmaceutical Co. Ltd.

e. Ethypharm, S.A. Ethypharm, S.A., is 99.09% owned by Financiere Verdi, and no publicly held corporation owns 10% or more of Ethypharm's stock.

4. The names of all law firms and partners or associates that appeared for the parties represented by me in the trial court or that are expected to appear in this court are:

Hogan Lovells US LLP: Eric. J. Lobenfeld, Catherine E. Stetson, Arlene L. Chow, Dillon Kim, Frederick Liu, Bonnie Chen, Takashi Okuda.

Hogan Lovells Horitsu Jimusho: Philippe Y. Riesen.

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/s/ Catherine E. Stetson
Catherine E. Stetson

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The material omitted throughout this brief relates to Zydus's ANDA product, Zydus's communications with FDA, and the basis for certain proprietary business decisions made by Zydus. That material is confidential and subject to a protective order in the District Court.

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STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, counsel for appellees states that no other appeal in or from the same civil action or proceeding in the District Court was previously before this or any other appellate court, and that counsel is not aware of any other case pending in this or any other court that will directly affect or be directly affected by this Court's decision in the pending appeal.

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NONCONFIDENTIAL
BRIEF FOR APPELLEES

JURISDICTION

The District Court had jurisdiction in this patent case under 28 U.S.C. § 1338(a). The District Court entered an interlocutory order continuing an injunction on October 23, 2012. JA 1.

Appellants filed a notice of appeal on November 19, 2012. JA 49-50. This Court has jurisdiction under 28 U.S.C. § 1292(c) of this appeal from an

interlocutory order described in § 1292(a)(1). *See Eli Lilly & Co.* v. *Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1349-50 (Fed. Cir. 2009).

COUNTERSTATEMENT OF THE ISSUE

Whether the District Court in this patent infringement action abused its discretion in extending for four additional months the statutory 30-month period during which the Food and Drug Administration's approval of a generic manufacturer's abbreviated new drug application may not become effective, where the generic manufacturer waited until mere weeks before trial, after the close of discovery, to .

COUNTERSTATEMENT OF THE CASE

Appellees Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals, LLC, and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda") own patents that claim the formulation for the brand-name drug Prevacid® SoluTab™. Appellee Ethypharm, S.A., also owns a patent that covers that formulation.

In 2010, appellants Zydus Pharmaceuticals USA, Inc., and Cadila Healthcare, Limited (together, "Zydus") filed an abbreviated new drug application ("ANDA") with FDA, seeking to manufacture a generic version of Prevacid® SoluTab™. Takeda and Ethypharm sued Zydus for patent infringement in federal district court. DE 1. The suit triggered a statutory 30-month stay prohibiting FDA from

declaring effective any approval of Zydus's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii).

Discovery and cross-motions consumed 2011 and over half of 2012. In September 2012—just five weeks before trial, and after the completion of discovery—Zydus . JA 258. Zydus asserted in court filings that meant its generic product could never literally infringe Takeda's patents. JA 175-176. In response to that late-breaking development, Takeda asked the District Court to adjourn trial, permit discovery on , and extend the statutory stay for a brief period to accommodate additional discovery that was necessitated . JA 217-218.

The District Court granted Takeda's requests. JA 2. Finding that Zydus had failed to reasonably cooperate in expediting the action, the court extended the stay for four additional months. JA 574. Zydus appealed.

COUNTERSTATEMENT OF THE FACTS

A. Statutory Framework

Before a brand manufacturer may market a new drug, it must seek FDA's approval through a new drug application ("NDA"). *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). The NDA must identify, among other things, each patent that claims the drug the brand manufacturer seeks to market. 21 U.S.C. § 355(b)(1).

If FDA approves the NDA, another company may later seek permission to market a generic version of the drug by filing an abbreviated new drug application ("ANDA") with FDA. *Caraco*, 132 S. Ct. at 1676. Typically, an ANDA must show that the generic drug is biologically equivalent to the brand manufacturer's drug. 21 U.S.C. § 355(j)(2)(A). An ANDA must also contain a certification with respect to each patent that claims the brand-name product or its use. *Id.* § 355(j)(2)(A)(vii). Among the possible certifications that an ANDA may make is that "such patent is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." *Id.* § 355(j)(2)(A)(vii)(IV). This is known as a "paragraph IV" certification. The statute requires that the generic manufacturer give notice of the certification to the brand manufacturer and other patentees. *Id.* § 355(j)(2)(B).

"Filing a paragraph IV certification means provoking litigation," *Caraco*, 132 S. Ct. at 1677, because a paragraph IV certification is itself an act of patent infringement under the statute. 35 U.S.C. § 271(e)(2)(A). If, within 45 days after receiving notice, a patentee files an infringement suit against the generic manufacturer, the statute prohibits FDA from making effective any approval of the generic drug for a period of 30 months, beginning on the date the notice was received. 21 U.S.C. § 355(j)(5)(B)(iii).

The statutory stay may be shorter or longer, depending on the circumstances. For instance, "if before the expiration of [the 30-month] period the district court decides that the patent is invalid or not infringed," the stay generally expires on the date the district court enters judgment. *Id.* § 355(j)(5)(B)(iii)(I)(aa). Conversely, "if before the expiration of such period the district court decides that the patent has been infringed," the stay could remain in place until the patent itself expires. *Id.* § 355(j)(5)(B)(iii)(II)(bb).

The statute also gives the district court discretion to shorten or lengthen the 30-month period if "either party to the action failed to reasonably cooperate in expediting the action." *Id.* § 355(j)(5)(B)(iii). If, for example, a party's failure to reasonably cooperate threatens to prevent the district court from rendering a decision on the merits before the expiration of the 30-month period, the district court could, in its discretion, extend the period. If the district court then renders a decision before the expiration of that extended period, the rules above would apply: The stay would generally end on the date of the court's judgment if the court finds the patent invalid or not infringed, and the stay could remain in place until the patent itself expires if the court does find it infringed.

B. Factual And Procedural Background

In 2002, FDA approved Takeda's NDA for lansoprazole orally disintegrating tablets (hereinafter called the "ODT product" or just "the product"),

which Takeda manufactures and sells under the brand name Prevacid® SoluTab™. DE 1, at 6. FDA lists four patents as claiming the ODT product: three owned by Takeda, and one owned by Ethypharm. Each of Takeda's three patents requires that the product contain enteric-coated or mannitol-finished granules of an average particle diameter of 400 µm or less. JA 79, 102, 124.

In 2010, Zydus filed an ANDA seeking FDA's approval to manufacture a generic version of Prevacid® SoluTab™. With its ANDA, Zydus submitted a paragraph IV certification asserting that Takeda and Ethypharm's listed patents were invalid or would not be infringed by manufacture of the generic version. Takeda and Ethypharm received notice of the certification in February 2010. DE 1, at 7. They sued Zydus in April 2010, within the 45-day window, meaning that FDA was statutorily prohibited from making any approval of the ANDA effective before August 2012—30 months following the receipt of notice. DE 1; 21 U.S.C. § 355(j)(5)(B)(iii).

The District Court held a *Markman* claim-construction hearing in May 2011, and issued an opinion construing disputed patent claim terms the following October. DE 113. In that opinion, the court construed the "average particle diameter" limitation in each of Takeda's patents as incorporating a measurement variation of ±10 percent. DE 113, at 7, 9-10. Thus, Takeda's patents would be literally infringed by a generic version of the ODT product containing granules

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with an average particle diameter of 440 µm or less. At the time, Zydus's

. JA 544, 545, 550.

The District Court denied Zydus's motion for reconsideration of its claim-construction order in January 2012. DE 130. By that time, the parties were already well into discovery. Takeda had conducted extensive testing of Zydus's ANDA product, and the parties had exchanged competing expert reports. JA 218. Takeda's expert report, for its part, stated that

. JA 218.

In March 2012, one of Zydus's outside counsel mentioned to Takeda's counsel in an email regarding a new batch of the generic ODT product that Zydus was

. JA 366-367. Zydus explained that

. JA 367. Rather, according to Zydus's counsel,

and thus unobjectionable to FDA. JA 366.

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A month passed. Zydus did not . Then, in April,

. *See* JA 233-234.

JA 233, 541-542.

JA 233.

Zydus still did not . Discovery in the infringement action continued. The parties agreed to service of rebuttal expert reports by the end of August 2012 and completion of expert discovery by the end of September. DE 220. The District Court ordered that pretrial motions be filed no later than September 28, and that trial begin on November 5. DE 219. Both sides consented to an extension of the 30-month stay from August to , to allow the District Court to try the case and render a decision before the stay expired. Zydus Br. 13.

On September 27—the day before pretrial motions were to be filed, and almost one year after the District Court had construed Takeda's patents to cover tablets with granules 440 µm or less in diameter—Zydus

. JA 258.

JA 234-257.

Takeda did not learn about until the next day, the deadline for the parties' pretrial motions, when Zydus filed a motion in limine seeking to preclude the introduction of any evidence regarding . JA 170. According to Zydus, all of the evidence and expert testimony Takeda had developed at great expense during the previous months of discovery was , which, in Zydus's view, demonstrated that the generic product it planned to market would not infringe Takeda's patents. JA 175-176.

In response to Zydus's unexpected motion in limine, Takeda argued that did not resolve the issue of infringement, because . JA 220. Indeed, the parties had contested throughout expert discovery . A new round of discovery was necessary, Takeda argued, to explore the ramifications of . JA 224-225. Takeda

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urged the District Court to adjourn trial, allow for limited additional discovery, and order a modest further extension of the statutory stay. JA 217-218.

After a hearing, the District Court agreed with Takeda. The court found that with

JA 574. The court thus concluded that it was

—four months beyond the previous expiration date agreed to by the parties. JA 2, 574. The court also denied Zydus's motion in limine without prejudice, adjourned trial pending further order, and granted Takeda's request to reopen discovery. JA 2.

Zydus filed an interlocutory appeal of the District Court's order extending the stay. FDA has not approved Zydus's ANDA. There is no indication that it is even close to doing so.

SUMMARY OF THE ARGUMENT

This case furnishes a textbook example of a party's failure to reasonably cooperate in expediting resolution of an infringement action. One of the central issues in this suit is whether

. The District Court in the fall of 2011 had issued a claim-construction order construing that range, and the parties

had conducted—and completed—months of costly discovery on the issue. But nearly a year after the claim-construction order, and as trial drew near, Zydus

a new theory of non-infringement that Zydus had not previously presented in court.

Zydus could have months before it did so. Instead, it waited until trial was imminent—by which time the parties had spent many months and many thousands of dollars on fact and expert discovery concerning

. The delayed timing of Zydus's

deprived Takeda of an adequate opportunity for discovery, including additional testing, about the ramifications of Zydus's and new theory of the case. Indeed, far from resolving the issue of infringement, Zydus's

only raises more questions about

. Given Zydus's failure to reasonably cooperate in expediting the action, the District Court acted well within its discretion in extending the stay for four months—time enough for the parties to conduct discovery concerning, and for the court to render a considered decision on the merits of, Zydus's late-arriving theory of non-infringement.

ARGUMENT

I. STANDARD OF REVIEW

"On procedural issues not unique to patent law, [this Court] appl[ies] the standard of review of the regional circuit." *Dominant Semiconductors Sdn. Bhd.* v. *OSRAM GmbH*, 524 F.3d 1254, 1260 (Fed. Cir. 2008) (internal quotation marks omitted). As in *Eli Lilly*, however, this Court need not decide whether extension of the 30-month stay is a procedural issue unique to patent law, because both this Court and the regional circuit—here, the Third Circuit—review discovery and case-management decisions only for abuse of discretion. *See Eli Lilly*, 557 F.3d at 1350; *ZF Meritor, LLC* v. *Eaton Corp.*, 696 F.3d 254, 268 (3d Cir. 2012). Zydus agrees. Zydus Br. 29.

"[D]eference * * * is the hallmark of abuse-of-discretion review." *Gen. Elec. Co.* v. *Joiner*, 522 U.S. 136, 143 (1997). Under that standard, this Court does not disturb a district court ruling unless it "is based on clearly erroneous findings of fact, is based on erroneous interpretations of the law, or is clearly unreasonable, arbitrary or fanciful." *Cybor Corp.* v. *FAS Techs., Inc.*, 138 F.3d 1448, 1460 (Fed. Cir. 1998) (en banc).

II. THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION BY EXTENDING THE STAY.

When a brand manufacturer sues a generic competitor for infringement after receiving a paragraph IV certification, the governing statute—the Food, Drug &

Cosmetic Act—provides that "each party shall reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii). Failure of a party to do so authorizes the district court to extend the statutorily imposed 30-month period during which FDA may not make effective any approval of the generic manufacturer's ANDA. *Id.*

In this case, the 30-month period was originally scheduled to expire in August 2012. The parties, however, agreed to extend the stay to , in order to give the District Court enough time to issue a decision on the merits before the stay expired. Zydus Br. 13. Zydus challenges only the District Court's subsequent discretionary decision, in light of Zydus's , to extend the stay for an additional four months, .

Zydus's challenges are meritless. The District Court expressly found that Zydus failed to reasonably cooperate in expediting the action by depriving Takeda of an adequate opportunity for discovery. The record fully supports that finding, which more than justifies the short four-month extension. There was no abuse of discretion.

A. Zydus Waited Until Mere Weeks Before Trial To , Despite Ample Opportunity To Do So Earlier.

A critical issue in this infringement action is the scope of a limitation contained in each of Takeda's three asserted patents: that the enteric-coated or mannitol-finished granules of the ODT product have an average particle diameter of no more than 400 µm. JA 79, 102, 124. The parties disputed the scope of this

limitation throughout the *Markman* proceedings, but in its October 2011 decision, the District Court agreed with Takeda, based on the patent's intrinsic evidence and expert testimony, that the limitation covered granules whose average particle diameter was measured to be 10 percent above the 400-µm figure. DE 113, at 7, 9-10. Thus, by October 2011, Zydus was well aware that it would infringe the particle-size limitation if it manufactured a generic product with granules 440 µm or less in average diameter.

Yet Zydus waited nearly a year, until late September 2012, to

. JA 258. By then, the parties had already engaged in extensive and costly discovery regarding

. Indeed, Zydus's came one month after the parties had traded rebuttal expert reports and one week after they had completed expert discovery altogether. DE 220. Takeda did not receive notice of Zydus's until the deadline for filing pretrial motions on September 28—a mere five weeks before trial was scheduled to begin. DE 219.

There was no justification for that delay. As Zydus acknowledges, the decision to

Zydus Br. 5 (emphasis added). In other words, it was a decision driven solely by

. Zydus could then assert that, in its view at least, its generic product "would never literally infringe the claims of the Takeda Patents-in-suit." *Id.* at 6. Once the District Court construed the upper range to be 440 µm, therefore, nothing held Zydus back from .

Statements made by Zydus's counsel in March 2012 confirm this fact. In an email message that month, Zydus's counsel explained that

JA 366-367.

Zydus's decision whether and when to

. Nor was it constrained by anything having to do with Zydus's . As Zydus's counsel explained in a separate email message, "[n]othing has changed in the overall process and the exact processes set forth in the ANDA filing are being followed." JA 366; *see also* Zydus Br. 27 ("Zydus's

does not alter in any way the formulation or manufacturing process of Zydus's ANDA product."). As counsel understood it,

—"something," he noted, "the FDA will not object to." JA 366. Accordingly, Zydus could have

any time after the claim-construction decision in October 2011; instead, it waited almost a year—until five weeks before trial—to do so.

Zydus contends that these and other communications put Takeda on notice before September 2012 that Zydus intended to . Zydus Br. 7. Not so. Zydus made no commitment to such ; its counsel described as merely "contemplated." JA 366. And in any event, Takeda obviously has no ability, let alone any obligation, to conduct discovery of *before* they are actually made. It is unreasonable for Zydus to demand, in essence, that Takeda prepare for not one, but two, trials in the spring and summer of 2012: one on , and another on .

Zydus also contends that it had "no choice but to delay in September. Zydus Br. 23. That is because, according to Zydus and its expert, *Id.* at 9 (citing JA 403-404 (Morrison Decl.)). Even if true (and Takeda has not taken discovery of that expert, who was disclosed only recently), that is irrelevant. First off, as noted above, the claim-construction ruling issued in October 2011;

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. Moreover, the timing of when FDA will *consider*

has no bearing on the timing of when

. After all, in this case was still pending on September 27, 2012, when Zydus . And remains pending to this day. It is thus simply not true that Zydus had "no choice but to delay" until September. Zydus Br. 23. Zydus could have any time after the District Court's *Markman* opinion in October 2011. But Zydus delayed for nearly a year, until discovery had already ended and trial was about to begin.

B. Zydus's Delay In Deprived Takeda Of An Adequate Opportunity For Discovery.

In an action brought by a brand manufacturer against a generic competitor who has filed a paragraph IV certification, "the statute requires an infringement inquiry focused on what is likely to be sold following FDA approval. This inquiry must be based on all of the relevant evidence, including the ANDA." *Glaxo, Inc.* v. *Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997).

When it , Zydus

JA 544, 545, 550.

This, in turn, allowed Zydus to introduce a new

theory into the case as part of its admittedly strategy: that because , its product "would never literally infringe the claims of the Takeda Patents-in-suit." Zydus Br. 5-6.

As the District Court found, Zydus's last-minute

JA 574. Up to that point, neither the District Court nor Takeda had reason to consider the theory of non-infringement that Zydus raised for the first time in its September 28 motion in limine. And with only five weeks left before trial, there was insufficient time for either the court or Takeda to fully explore the ramifications of Zydus's new theory. After all, discovery pertaining to Zydus's had lasted for months, involving extensive product testing and numerous expert reports.

Zydus argues, however, that no such additional discovery pertaining to its is necessary. For support, it cites one case: *Bayer AG* v. *Elan Pharmaceutical Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000) ("*Elan*"). Zydus Br. 30-32. *Elan* involved a patent of Bayer's claiming a drug containing nifedipine crystals of a specific surface area, up to 4 m^2/g. 212 F.3d at 1246. Elan filed an ANDA, and Bayer brought an infringement action. *Id.* Elan later amended the ANDA to specify that its tablet contained crystals of a specific

surface area of 5 m^2/g or greater. *Id.* This Court subsequently affirmed the district court's grant of summary judgment for Elan, concluding that "the specification in Elan's ANDA defines its product in a way that directly addresses the question of infringement—the [specific surface area] of the nifedipine crystals." *Id.* at 1249. And "[a]lthough there may be factual issues as to whether Elan can comply with its specification, they are not material factual issues because 21 U.S.C. § 331(d) prohibits Elan from selling any product that does not meet its ANDA's requirements." 212 F.3d at 1250.

Zydus contends that . Zydus Br. 27. Not so. In *Elan*, the additional ANDA specification "directly address[ed] the question of infringement"; Bayer did not dispute that if the generic manufacturer complied with the specification, there would be no infringement. 212 F.3d at 1249-50. When, however, the generic can comply with its additional ANDA specification and still infringe the patents, the generic's specification does not directly address the question of infringement. *See id.*; *Glaxo*, 110 F.3d at 1567-70. In such a case, the court must consider "other evidence"—beyond the ANDA itself—"to determine what product the applicant is 'likely' to produce pursuant to its ANDA." *Apotex, Inc.* v. *Cephalon, Inc.*, No. 2:06-cv-2768, 2012 WL 1080148, at *8 (E.D. Pa. Mar. 28, 2012).

This Court confronted just such a circumstance in *Bayer AG* v. *Biovail Corp.*, 279 F.3d 1340 (Fed. Cir. 2002) ("*Biovail*")—a decision that tellingly goes unmentioned in Zydus's brief. That decision—issued two years after *Elan*—involved the same patent in *Elan* and a "nearly identical" ANDA. *Id.* at 1346. Biovail contended that Bayer was collaterally estopped from claiming infringement because, just as in *Elan*, the ANDA had specified a nifedipine-crystal surface area of 5 m^2/g or greater. *See id.* at 1343, 1346. This Court, however, concluded that *Elan* was not controlling, and remanded the case for further proceedings, including discovery. *Id.* at 1346, 1349. The difference between *Elan* and *Biovail* was that in the latter case, Bayer introduced evidence raising a "legitimate question" as to whether the tablet could be made in strict conformity with the ANDA and nevertheless infringe the patent. *Id.* at 1346. Indeed, the evidence showed that the crystals could have a surface area of 5 m^2/g or greater *before* tablet manufacture—thus complying with the ANDA—but that their surface area could shrink below 4 m^2/g *after* tablet manufacture—thus potentially infringing the patent. *See id.* at 1346-47. The ANDA thus did not directly resolve the question of infringement.

JA 220.

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The parties and their experts dispute whether

. JA 560.

. JA 220. But if

.

Zydus's

. *See* JA 220. There are different methods. Zydus previously has used what is known as

. JA 220 n.3. But as Takeda's experts have opined,

. JA 279-280, 560-561. Takeda's experts also have explained that

. JA 220 n.3, 281. A batch of generic product may comply with Zydus's ANDA

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. The same batch may infringe the Takeda patents

.

As the foregoing demonstrates, there are,

Abbott Labs.

v. *TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002). It was hardly unreasonable for the District Court to conclude that these disputes could be resolved only by targeted discovery concerning what is likely to be sold pursuant to . Nor was it unreasonable for the District Court to conclude that by waiting until a month before trial to , Zydus deprived Takeda of an adequate opportunity for such discovery. The District Court therefore did not abuse its discretion by finding that Zydus failed to reasonably cooperate in expediting the action.

This Court's decision in *Eli Lilly* supports this conclusion. In that case, a generic manufacturer amended its ANDA "late in the litigation" to include a new particle-size measuring methodology. 557 F.3d at 1350. In addition, the generic manufacturer did not provide batch samples of its ANDA product to the plaintiff until after the discovery deadline set by the district court. *Id.* at 1346. This Court affirmed the district court's grant of a four-month extension of the statutory stay, holding that the record supported the district court's finding that the generic

manufacturer failed to cooperate in expediting the litigation. *Id.* at 1351. The present case involves an even more egregious set of facts: The generic company in *Eli Lilly* amended its ANDA *eight months* before trial, *id.* at 1349, and still was found not to have cooperated in expediting the litigation. Zydus here *five weeks* before trial, after the deadline for completing discovery had passed. This is an even easier case for affirmance than *Eli Lilly*.

Zydus tellingly does not discuss *Eli Lilly*—other than citing it for the deferential standard of review owed the District Court's decision. Instead, Zydus cites a handful of district court decisions *denying* extensions of the 30-month stay, and argues from those different decisions that this District Court must have abused its discretion in *granting* a stay. Zydus Br. 30, 36 (citing *Shire LLC* v. *Watson Pharms., Inc.*, No. 11 Civ. 2340, 2012 WL 4477605 (S.D.N.Y. Sept. 25, 2012); *Bayer Schera Pharma AG* v. *Sandoz, Inc.*, No. 08 Civ. 3710, 2010 WL 3447906 (S.D.N.Y. Sept. 2, 2010); *In re Brimonidine Patent Litig.*, No. 07-md-1866, 2008 WL 4809037 (D. Del. Nov. 3, 2008)). None of those decisions involved a last-minute . But even if the facts of those cases were at all analogous to the facts here, they would not bear on the question before this Court: whether the District Court abused its discretion by granting the extension. One court's *denial* of an extension does not restrict another court's discretion to *grant* an extension, in a different case presenting different

facts. The entire point of a deferential standard of appellate review is to preserve a trial court's discretion to address different circumstances in different ways. The cases Zydus cites fail to establish that the District Court's judgment should be overridden here.

C. A Four-Month Extension Was Reasonable Under The Circumstances.

The parties had already agreed to extend the 30-month stay from August to , so the effect of the District Court's order was merely to extend the stay for an additional four months, . Given Zydus's failure to cooperate reasonably in expediting the action, the District Court acted well within its discretion in granting an extension of that length. *See Eli Lilly*, 557 F.3d at 1349, 1351 (affirming the grant of a four-month extension). A four-month extension will allow Takeda to explore the ramifications of Zydus's new theory of non-infringement based on . It will allow the parties to conduct limited fact and expert discovery concerning what Zydus is likely to sell pursuant to . And it will allow the District Court the time it needs to render a decision on the merits before the stay expires.

CONCLUSION

For all of the foregoing reasons, the District Court's order extending the statutory stay should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 5435 words.

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the typestyle requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office Word in Times New Roman 14-point font.

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of January 2013, I caused a copy of the nonconfidential version of the foregoing Brief for Appellees to be served by electronic means via the Court's CM/ECF system on all counsel registered to receive electronic notices.

I further certify that I caused two copies of the confidential version of this brief to be served via first-class mail upon the following:

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